

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte THEODORE HERSH M.D.

Appeal No. 2001-1177
Application No. 08/781,868

ON BRIEF

Before ADAMS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 35-54, all of the claims remaining. Claims 35, 36, 39-43, and 45 are representative and read as follows:

35. A composition for enhancing repair from free radical damage to skin as a result of treatment of the skin with exfoliants, chemosurgery or laser therapy comprising as active ingredients glutathione and selenoamino acid in amounts suitable for enhancing repair of skin from free radical damage, said active ingredients being combined with a suitable carrier for topical application.

- 36. The composition of claim 35 further comprising acetyl-L-carnitine.
- 39. The composition of claim 35 further comprising epidermal growth factor.
- 43. The composition of claim 35 further comprising tissue respiratory factor.
- 45. A method for enhancing repair from free radical damage to skin as a result of treatment of the skin with exfoliants, chemosurgery or laser therapy comprising topically applying active ingredients in a suitable topical carrier to skin damaged by exfoliants, chemosurgery or laser therapy, said active ingredients comprising glutathione and selenoamino acid in amounts suitable for enhancing repair of skin from free radical damage.

The examiner relies on the following references:

Levin	4,942,031	Jul. 17, 1990
Spector et al. (Spector)	5,128,365	Jul. 7, 1992
Burke	5,330,757	Jul. 19, 1994
Finkenaur et al. (Finkenaur)	5,427,778	Jun. 27, 1995
N'Guyen et al. (N'Guyen)	5,516,507	May 14, 1996
Piazza et al. (Piazza)	5,565,439	Oct. 15, 1996
Otsu et al. (Otsu)	5,582,817	Dec. 10, 1996
Cavazza et al. (Cavazza)	5,627,212	May 6, 1997
Hersh et al. (Hersh)	5,667,791	Sep. 16, 1997

Claims 35, 36, and 38 stand rejected for obviousness-type double patenting over claims 1, 3, and 5-7 of Hersh.

Claims 35-54 stand rejected under 35 U.S.C. § 102(e) as anticipated by Hersh.

Claims 35, 37, 38, and 44 stand rejected under 35 U.S.C. § 103 as obvious in view of N'Guyen and Burke.

Claims 36 and 39-43 stand rejected under 35 U.S.C. § 103 as obvious in view of N'Guyen and Burke, combined with one of the following references:

Cavazza, Piazza, Otsu, Levin, Finkenauer, or Spector.

Claims 45-54 stand rejected under 35 U.S.C. § 103 as obvious in view of N'Guyen, Burke, Cavazza, Piazza, Otsu, Levin, Finkenauer, and Spector.

We affirm the rejection of the composition claims (claims 35-44) but reverse the rejection of the method claims (claims 45-54).

Background

“Skin peeling programs (chemical or thermal peels) are designed to remove ‘dead’ skin with the aim of being replaced by new, clearer and younger cells yielding smooth and firmer skin.” Specification, page 1. Such therapies are used to treat, among other things, sun-damaged skin and fine lines. See id. However, these therapies can also result in damage to the skin, resulting from the generation of free radicals. See id., page 8.

The specification discloses “a composition and method for reducing the cutaneous effects and complications of chemosurgery and laser therapy of induced skin damage. The composition comprises an effective amount of a glutathione and selenoamino acid since selenium is a co-factor of glutathione peroxidase.” Page 13. The specification also discloses that the “composition can be formulated as a lotion containing from about 0.01% to 10% of the above described active ingredients.” Page 27. The specification discloses several exemplary compositions that contain 0.03% glutathione and 0.03% selenomethionine. See pages 28-29 (“reparative hand and nail formula”), 32-33 (“protein gel masque”), 34-35 (“sunburn lotion”), 37-38 (“sun gel”), and 38-40 (“reparative cream”).

Discussion

According to Appellant, the composition claims stand or fall together and the method claims stand or fall together. See the Appeal Brief, page 5.

Therefore, where multiple claims have been rejected on the same basis, we have considered claim 35 as representative of the composition claims and claim 45 as representative of the method claims. See 37 CFR § 192(c)(7).

1. Obviousness-type double patenting

The examiner rejected claims 35, 36, and 38 under the judicially-created doctrine of obviousness-type double patenting, on the basis that these claims are not patentably distinct from claims 1, 3, and 5-7 of Appellant's issued patent 5,677,791 ("Hersh"). We agree. Instant claim 35 is directed to a composition comprising glutathione and selenoamino acid "in amounts suitable for enhancing repair of skin from free radical damage." The specification states that the claimed "composition can be formulated as a lotion containing from about 0.01% to 10% of the above described active ingredients." Page 27. The specification also provides exemplary compositions containing 0.03% glutathione and 0.03% selenomethionine.

Claim 1 of Hersh is directed to a composition for topical application comprising at least 0.01% selenomethionine and at least 0.03% glutathione. Thus, the instantly claimed composition and Hersh's compositions contain the same ingredients in the same amounts. Instant claim 35 is therefore anticipated

by the composition of Hersh's claim 1 and a rejection for obviousness-type double patenting is appropriate. See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 968, 58 USPQ2d 1869, 1878 (Fed. Cir. 2001) ("A later . . . claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim."). See also In re Goodman, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993) ("[The application claims] are generic to the species of invention covered by claim 3 of the patent. Thus, the generic invention is 'anticipated' by the species of the patented invention. This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generic application." (citation and footnote omitted)).

Appellant argues that "[a]lthough the composition of applicant's own '791 patent and those described herein are similar, they are used for a different purpose. . . . From a compositional standpoint, the amounts of ingredients oftentimes vary as well as the type of carrier as the intended purpose for these compositions are completely unrelated." Appeal Brief, page 6.

This argument is not persuasive. It is true that the patent's claims are directed to a "composition for protection from x-ray induced skin damage," while the instant claims are directed to a "composition for enhancing repair from free radical damage to skin as a result of treatment of the skin with exfoliants, chemosurgery or laser therapy." The difference in the preambles of the claims, however, merely reflects the intended use of the compositions. The preamble language therefore does not distinguish the patented composition from that of the

instant claims. See Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999): “If . . . the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention’s limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction.”

Appellant has presented no evidence that a composition comprising a topical carrier and, e.g., 0.03% glutathione and 0.03% selenomethionine, when used to enhance repair of skin following chemosurgery or laser therapy, would differ from the same composition when used to protect skin from x-ray induced damage. In this regard, we note that both the patent and the instant application disclose exemplary “reparative cream” compositions that contain apparently identical ingredients. See Hersh, column 13, line 50 to column 14, line 26, and the instant specification, pages 38-40.

2. Anticipation

The examiner also rejected all of the instant claims as anticipated by Hersh. The examiner characterized Hersh as disclosing the same compositions as are presently claimed, as well as a method of using such compositions to treat the skin. See the Examiner’s Answer, page 4.

“Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim.” Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). “[E]very

limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines. However, recitation, in a claim to a composition, of a particular property said to be possessed by the recited composition, be that property newly-discovered or not, does not necessarily change the scope of the subject matter otherwise defined by that claim.” In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). “It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.” In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

In this case, we agree with the examiner that Hersh anticipates the composition claims of the present application. Hersh discloses compositions comprising glutathione and selenoamino acids (e.g., selenomethionine) for topical treatment of skin. See, e.g., column 13, line 50 to column 14, line 26. As discussed above, Hersh’s exemplary “reparative cream” appears to be identical to the working example in the present specification. Hersh’s reparative cream composition comprises 0.03% glutathione and selenomethionine, the same concentration of these ingredients used in the working examples of the present specification. Thus, the prior art compositions appear to comprise glutathione and a selenoamino acid “in amounts suitable for enhancing repair of skin from free radical damage,” as required by the present claims. Claims 35-44 are anticipated by Hersh.

We do not find, however, that Hersh anticipates the method claims of the present application. Hersh does not teach using the disclosed compositions to

treat patients who have been subjected to exfoliation, chemosurgery, or laser therapy. Thus, Hersh does not disclose all of the limitations of the method claims.

With regard to the composition claims, Appellant “fully concurs that the compositions are similar,” but argues that “the end uses of these compositions are not similar.” Appeal Brief, page 6. Appellant argues that “[t]he preamble[s] of the composition claims differ dramatically as the reference is directed to protecting the skin from the ill effects of x-ray radiation while the present claims are directed to enhancing repair from free radical damage to the skin as a result of treatment of the skin with exfoliants, chemosurgery or laser therapy.” Id., pages 6-7.

This argument is not persuasive. It is true, of course, that the preamble of the present claims differs from the preamble of the patent’s claims. However, as discussed above, the preamble of the composition claims does not limit the claimed composition because it merely recited a purpose or intended use of the composition; it does not add any limitations to those in the body of the claims. Therefore, the preamble does not change the scope of the claims.

For the reasons discussed above, the rejection under 35 U.S.C. § 102(e) is affirmed with respect to claims 35-44 and reversed with respect to claims 45-54.

3. Obviousness

The examiner rejected all of the composition claims as obvious over N'Guyen and Burke, or N'Guyen and Burke in combination with one of six other references. The examiner also rejected all of the method claims as obvious over N'Guyen, Burke, and all six of the other references relied on with respect to the method claims.

A. N'Guyen and Burke

The examiner rejected claims 35, 37, 38, and 44 as obvious over N'Guyen and Burke. The examiner noted that N'Guyen discloses topical compositions comprising glutathione for treating or preventing cutaneous aging, while Burke discloses topical compositions comprising selenoamino acids for treating skin damage caused by UV irradiation. Examiner's Answer, pages 5-6. Burke discloses that the "cumulative damage caused by UV irradiation is denoted in the medical dermatologic literature as 'photoaging' and is manifested clinically by wrinkles [and] dry, waxy skin." Column 1, lines 25-28. The examiner concluded that these teachings would have rendered the presently claimed compositions prima facie obvious.

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d

1780, 1783 (Fed. Cir. 1992) (citations omitted). “It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art.” In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Here, we agree that N’Guyen and Burke render the composition of claim 35 prima facie obvious. N’Guyen and Burke teach compositions for treating skin aging and comprising glutathione and selenoamino acids, respectively. It would have been obvious to combine the active ingredients of the two compositions to make a third composition for treating skin aging, and comprising both glutathione and selenoamino acids.

Appellant concedes that N’Guyen and Burke “relate equally to compositions to repair cutaneous aging, called photoaging, by known dermatologic processes.” Appeal Brief, page 8. He argues, however, that the references do not support a prima facie case because they do not teach use of the disclosed compositions “for the repair of damage to the skin from chemical peels and thermal injury of laser surgery.” Id., page 9.

This argument is not persuasive. As discussed above, claim 35 is directed to a composition and the preamble’s recitation of the intended use of that composition does not limit the scope of the claimed composition. The prior art renders obvious a composition within the scope of claim 35, albeit for a

different use, and therefore claim 35 is unpatentable under 35 U.S.C. § 103.

Claims 37, 38, and 44 fall with claim 35.

B. N'Guyen, Burke, and Levin

The examiner rejected claim 43 as obvious over N'Guyen, Burke, and Levin. Claim 43 is directed to the composition of claim 35, with the additional component tissue respiratory factor. As the examiner noted, Levin teaches topical compositions comprising tissue respiratory factor for treating skin wrinkles, among other things. See Levin, column 1, lines 34-35 and 65-68. The examiner concluded that it would have been obvious to combine the tissue respiratory factor disclosed by Levin with the composition comprising glutathione and selenoamino acids taught by the combination of N'Guyen and Burke.

We agree. Levin teaches that tissue respiratory factor is useful in treating skin wrinkles, and Burke teaches that wrinkles are one of the symptoms of photoaging. Thus, it would have been obvious to combine Levin's tissue respiratory factor with the composition suggested by N'Guyen and Burke. See Kerkhoven, 626 F.2d at 850, 205 USPQ at 1072 ("It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.").

Appellant argues that "Levin teaches a topical composition including an anti-inflammatory agent and live yeast cell derivative to ameliorate the neuralgic pain associated with herpes infection when applied to an area of the skin proximate the pain. Once again, the combination of Levin with the principal

references of N'Guyen and Burke represents a classic case of hindsight.”

Appeal Brief, page 13. Appellant also argues that “even if such a composition was to be made, the composition, taken as a whole, would teach nothing about applicant’s composition.” Id.

This argument is not persuasive. First, Levin teaches that “live yeast cell derivative” is another name for tissue respiratory factor. See column 1, lines 21-24 (“LYCD as utilized herein . . . is the acronym for Live Yeast Cell Derivative. The material is also known as . . . Tissue Respiratory Factor (TRF).”). Levin also teaches that tissue respiratory factor is “suitable for the treatment of various ailments and physical conditions of the skin such as . . . wrinkles.” Column 1, lines 65-68. See also column 12, lines 1-62 (headed “Anti-Skin Wrinkling Compositions”). Thus, we do not agree with Appellant’s characterization of Levin as limited to compositions for treating pain associated with herpes virus infections.

Nor do we agree that the references could only be combined with the benefit of hindsight. As discussed above, all of the references disclose topical compositions for treating skin aging or a symptom thereof. It would therefore have been obvious to combine the active ingredients of the three prior art compositions in order to create a topical composition for treating skin aging comprising glutathione, selenoamino acids, and tissue respiratory factor. Such a composition meets all the limitations of claim 43, which is therefore unpatentable under 35 U.S.C. § 103.

C. The other combinations

The examiner rejected claims 36 and 39-42 as obvious over N'Guyen and Burke, further combined with Cavazza (claim 36), Piazza (claim 39), Finkenauer (claim 40), Spector (claim 41), or Otsu (claim 42). These references disclose each of the additional ingredients recited in the rejected dependent claims. However, we reverse these rejections because the references do not provide adequate motivation to combine their respective compositions.

Cavazza discloses compositions comprising acetyl-L-carnitine (see column 1, lines 8-11 and 28-29) for treating dermatoses such as ichthyosis and psoriasis (column 6, line 66 to column 7, line 3). Piazza discloses compositions comprising epidermal growth factor (column 12, lines 28-32) for treating hyperproliferative conditions such as cancer or psoriasis (column 2, lines 23-39). Finkenauer teaches compositions comprising fibroblast growth factor (column 1, lines 23-28) for treating wounds (column 1, lines 64-66). Spector teaches compositions comprising glutathione peroxidase activity for treating cataracts (column 4, lines 37-44). Otsu teaches compositions comprising cysteine (column 4, line 34) for treating skin diseases and screening UV rays (column 3, lines 1-6).

None of these references is addressed to the problem of skin aging that is the focus of N'Guyen and Burke. The examiner has not adequately explained why a person of skill in the art would have combined an ingredient disclosed to be useful for, e.g., treating psoriasis with other ingredients disclosed to be useful in treating skin aging.

The examiner argues that all of the references teach that the various agents are useful in treating damaged skin, and therefore it would have been obvious to combine them. In our view, this characterization overstates the breadth of the disclosures of Cavazza, Piazza, Finkenauer, Spector, and Otsu. These references disclose certain agents to be useful in treating skin that is suffering from a specific condition, not as useful in treating “damaged” skin generally, regardless of the source of the damage. Importantly, none of these references discloses the various agents to be useful in treating age-damaged skin, and therefore they would not have provided the requisite motivation to combine their respective agents with the glutathione and selenoamino acids taught by N’Guyen and Burke.

The rejection of claims 36 and 39-42 under 35 U.S.C. § 103 is reversed.

D. The method claims

The examiner rejected all of the method claims (claims 45-54) as obvious over the combined disclosures of N’Guyen, Burke, Levin, Cavazza, Piazza, Finkenauer, Spector, and Otsu. The examiner reviewed the disclosures of each of the cited references and concluded that

[e]ach of these references discloses methods of treating free radical damaged skin by applying compositions comprising one or more of the recited ingredients. These methods provide for the treatment of damaged skin, and/or the prevention of further damage to the skin. It would have been obvious to one of ordinary skill in the art to have used compositions comprising glutathione and selenoamino acids, as well as [the other recited agents] for the repair of free radical damaged skin, as these ingredients have been shown to be important and/or effective for the healing of free radical damaged skin, and other types of injuries or damage. Combination of these ingredients for use in the method of treatment would be

expected to increase the healing properties of the composition, therefore, the invention as a whole is prima facie obvious. . . .

Examiner's Answer, page 18.

We reverse this rejection. The examiner characterizes the rejected claims as directed to a "method of repairing free radical damage." However, the claims do not encompass a method of repairing any free radical damage, but are limited to a "method for enhancing repair from free radical damage to skin as a result of treatment of the skin with exfoliants, chemosurgery or laser therapy." This preamble language constitutes a limitation of the claimed method, because it excludes from the scope of the claimed method treatment of patients other than those who have suffered free radical damage to their skin as a result of exfoliants, chemosurgery, or laser therapy. Thus, although the preamble did not further limit the composition claims, it does limit the method claims. The examiner has pointed to nothing in the relied-on references that suggests that any of the disclosed agents are useful in treating skin damaged by exfoliants, chemosurgery or laser therapy. Thus, the examiner has not shown that the methods of claims 45-54 would have been prima facie obvious in view of the prior art.

Summary

The composition of claim 35 is anticipated by both the claims and disclosure of Hersh. The composition is also rendered obvious by the disclosures of N'Guyen and Burke. We, therefore, affirm the rejections of claim 35 for obviousness-type double patenting, anticipation, and obviousness. Claims

36-44 fall with claim 35. However, none of the cited references teaches or suggests a method of using a composition comprising glutathione and selenoamino acids for treating skin damaged by exfoliants, chemosurgery, or laser therapy, as required by claims 45-54. We therefore reverse the rejections of these claims.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)

AFFIRMED-IN-PART

Donald E. Adams)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Demetra J. Mills)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Eric Grimes)	
Administrative Patent Judge)	

MALCOLM B. WITTENBERG
FOUR EMBARCADERO CENTER
19TH FLOOR
P.O. BOX 7936
SAN FRANCISCO, CA 94120

EG/jlb